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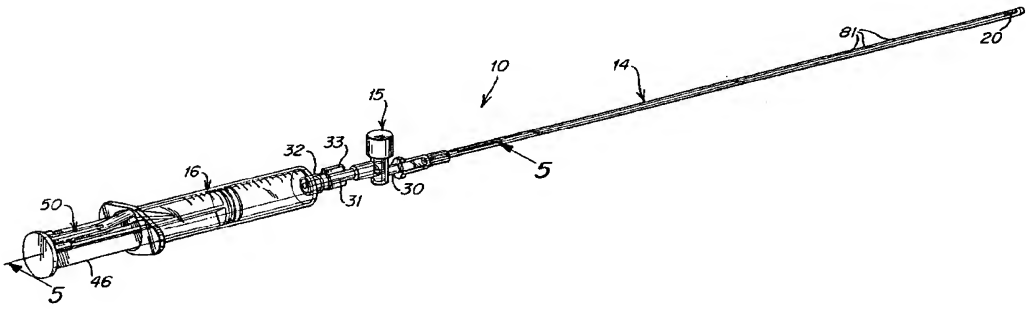
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: UTERINE SAMPLER



(57) Abstract: The uterine sampler for collecting body material from the uterus of an individual as a vacuum uterine catheter defining the sampling of an elongated body extending from the opening to a proximal end defining a vacuum passageway. A vacuum device having a vacuum chamber such as a syringe is used in connection with the vacuum passageway through a valve separating the vacuum chamber from the vacuum passageway which valve can be opened or closed by the hand of a user to create a vacuum in said vacuum passageway.

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UTERINE SAMPLER

FIELD OF THE INVENTION

This invention relates to a uterine sampling device for obtaining body materials for subsequent testing.

BACKGROUND OF THE INVENTION

Uterine samplers are known in the art for inter alia aiding in testing to aid in promoting the chance of pregnancy, aiding in hormone replacement therapy in connection with aging and the like and in determining factors relating to possible cancers in the body of women. Such samplers, such as Milex pipette and Unimar pipelle curette uterine samplers often have a vacuum passageway in an elongated syringe type catheter which is passed through the vagina directly into the uterus of an individual after which a vacuum is created by withdrawal of the plunger of the syringe. Cells aspirated are then checked for normal or abnormal characteristics. The material collected or sampled can be cells and tissue from the uterus lining or other cells which are capable of being studied when removed from the body. Such catheters often require careful manipulation and use of both hands of the user which can interfere with other procedures which the user may desire to carry out during the sampling procedure. Known samplers often have limited vacuum capacity due to the limited length of the plunger used within a small passageway uterine catheter. Tests for uterine cell and tissue samples and material collected from the uterus are voluminous and many millions of such tests are done every year.

SUMMARY OF THE INVENTION

It is an object of this invention to provide a uterine sampler which can be inexpensively formed of simple plastic parts which are capable of sterilization and use to simply and advantageously obtain desired material samples.

Still another object of this invention is to provide the uterine sampler in accordance with the preceding object which can be used by one hand of the user to carry out sample collection and can have a desired predetermined vacuum value useful in withdrawing samples from the uterus by the use of vacuum.

Still another object of this invention is to provide a uterine sampler in accordance with the preceding objects which can be reset after an initial use so that the uterine sampler can be re-used in the same individual to obtain additional sampling materials and which will allow sample collection continuously as moved into and out of the uterus or at separate times if desired.

Still another object of this invention is to provide the uterine sampler in accordance with the preceding objects wherein a vacuum value can be predetermined and at least one vacuum value can be used with a first stop while a second vacuum value can be obtained by use of a second stop.

Still another object of this invention is to provide the uterine sampler which has an orientation indicator which enables a user to determine the position of a collection orifice within the body in use of the device and which orifice can gently obtain samples without scarring the uterus.

According to the invention, a uterine sampler for collecting a sample of body material from the uterus of an individual has a tubular uterine catheter defining a sampling opening preferably at a distal end and an elongated body extending from said opening to a proximal end with the catheter body defining an axially extending vacuum passageway. A vacuum device having a vacuum chamber for use in creating a vacuum in the vacuum passageway is attached to the vacuum passageway through a gate located between the vacuum device chamber and the vacuum passageway to interconnect and disconnect the chamber from the passageway by manipulation of the gate by the hand of the user.

Preferably the vacuum uterine catheter is connected to a resiliently biased closed valve which can be manipulated by the hand of the user while the hand of the user grasps the vacuum device. The vacuum device is preferably a syringe having a plunger and the valve and uterine catheter are interconnected by Luer locks or suitable connection means. When the catheter has a length of preferably about 25 centimeters, a conventional 10 centimeter syringe having an axial length of less than the catheter length can be used with a plunger and vacuum chamber sufficient to predefine a vacuum in the syringe. Thus, a user can withdraw the plunger, create a predetermined vacuum by means of a stop which holds the plunger in withdrawn position and the user manipulates the syringe to place the catheter in the uterus of the body through the vagina, whereupon any finger

of the user can depress an actuating handle of the valve to create a desired degree of vacuum in the catheter. Full depression would equalize the vacuum in the syringe and catheter while partial or alternate compressions would allow differing amounts of a vacuum to be created in the catheter as for example when the catheter is moved within the body to different collection zones.

According to the invention, in a method of obtaining material samples from the uterus of an individual, an elongated catheter having a sample collecting opening aligned with the vacuum passageway, which is in turn connected with a resiliently biased closed valve and a vacuum chamber holding a predetermined vacuum, is introduced into the body by insertion through the vagina into the uterus at a predetermined length. The valve is manipulated by the hand of the user which inserts the catheter to create a vacuum in the vacuum passageway, which vacuum is derived from the vacuum device having a preset vacuum. The syringe having sample material in the vacuum catheter is then withdrawn to obtain desired samples. The samples can be expelled for testing by use of pressure from the syringe. In some methods, the vacuum within the catheter is varied by multiple openings and closings of the resiliently biased valve, while in some uses, the valve is fully opened for a single vacuum value.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other features of the present invention will be better understood from a reading of this specification in conjunction with the attached drawings in which:

FIG. 1 is a side perspective view of a preferred embodiment of a uterine sampler in accordance with this invention;

FIG. 2 is a top plan view thereof;

FIG. 3 is a top view axial cross-sectional through a distal end shown in line 3-3 of FIG. 2;

FIG. 4 is a side cross-sectional view through line 4-4 of FIG. 3;

FIG. 5 is a side axially extending cross-sectional view of a portion of the uterine sampler shown in FIG. 1;

FIG. 6 is a cross-sectional view through line 6-6 of FIG. 5;

FIG. 7 is an exploded view of a stop and plunger of the preferred embodiment of this invention;

FIG. 8 is a cross-sectional view through the embodiment of FIG. 2 showing the syringe plunger in a first starting position;

FIG. 9 is an axially extending cross-sectional view in accordance with FIG. 8 showing a first position of the plunger of the syringe to create a vacuum;

FIG. 10 is a cross-sectional view in accordance with FIG. 9 showing the valve actuating handle depressed to open the valve after the device is inserted in the body allowing the vacuum from the syringe to cause a vacuum in the catheter within the body to enable collection of fluid or cellular body materials within the catheter;

FIGS. 11 and 12 are cross-sectional views showing respectively a stop position of the stop as in FIG. 11 and a release position in FIG. 12;

FIG. 13 shows a cross-sectional view through the central axis of the uterine sampler as in FIGS. 11 and 12 where the plunger is depressed and moved to expel materials in the collection area of the uterine catheter to allow testing of the material and/or reuse in the same individual, of the catheter and/or sample collection from that individual;

FIG. 14 is an axial cross-sectional view through the center of a second embodiment of the present invention where the syringe plunger carries two stop members enabling different values of vacuum to be created in the vacuum chamber as desired.

DETAILED DESCRIPTION

A uterine sampler 10 for collecting a sample of body material 11 (FIG. 13) from the uterus and body 12 (FIG. 10) of an individual is shown in FIG. 1 to have a tubular vacuum uterine catheter 14, a gate or valve 15 and a tubular syringe 16 carrying a first vacuum stop 17. The vacuum uterine sampler can be assembled as shown in FIG. 1 or disassembled into two or more pieces at Luer locks as will be described.

The vacuum uterine catheter 14 defines a sampling orifice or opening 20 at a distal end with a tubular axially extending vacuum passageway 21 extending to a Luer lock at a proximal ending 22 of substantially conventional size and configuration. The axially extending catheter 14 provides a orifice or opening 20 having a rim diameter 23 at a surface greater than a rim diameter 24 within the catheter. This structure provides a

gentle action to the lining of the uterus while still allowing sufficient collection of sample material such as body cells and the like.

The vacuum uterine catheter body is preferably formed of a polycarbonate such as a clear polycarbonate obtained from Bayer Corporation of Pittsburgh, PA. However, the catheter can be formed of other materials such as polyethylene, polypropylene, clear or opaque plastics as desired. Clear materials are preferred in order to enable the user to review the sample collected when the sampler is removed from the body.

Preferably polycarbonates are used since they enable bending with retention of the bend at the tip end to enable certain procedures to be used by the test collector using the uterine sampler. The vacuum passageway is preferably formed by a tube approximately 25 centimeters long, but can vary from 20 to 30 centimeters and greater depending upon the user's preference. The tube preferably has a thickness of from 0.43 to 0.48 millimeters with a plug 26 closing the ending and adhesively attached to the tube 25. Thicker or thinner tube walls can be used. A Luer lock female ending is preferably attached to the end of the tube 25 as best shown in FIGS. 1-11 and can be adhesively bound to a Luer lock small tube of a valve 15. In some cases, a pressure fit of the Luer lock is used without adhesive.

Preferably the uterine catheter 14 is tubular and preferably cylindrical extending axially to the proximal end of the device. The catheter can be marked with axially spaced indicia such as centimeter markings 81 so that the user can determine the depth of penetration of the catheter 14 in use in the body.

The gate or valve 15 is preferably of a standard type as sold for example as Trac-Valve assembly S54026315 by B. Braun of Allentown, PA. The valve has a male Luer conduit 30 and a female Luer connector 31 which female connector attaches to a Luer stub 32 of a conventional syringe. The Luer connector 31 has wings 33 to enable twisting on or off the valve into the assembled position. Here again, all of the Luer connections can be attached by conventional adhesives as known in the art or joined by pressure Luer connections.

Valve 15 is spring loaded to a closed position as best shown in FIG. 5. The coil spring 35 biases an end cap or actuating handle 36 to an up position with a valve stem or plunger 37 allowing actuation of a passageway stop 34. Thus, depression of the cap 36

by the hand of the user enables flow of air as shown in FIG. 10 once a vacuum has been created in the vacuum chamber 40 of the cylindrical barrel 41 of the syringe.

FIGS. 8, 9, and 10 show various positions of the resiliently biased valve 15. Note for example at a starting position at FIG. 8, the plunger 46 is depressed, all parts are attached and the valve 15 is closed. The plunger 46 is then withdrawn as shown in FIG. 9 to create a vacuum in the chamber 40 with a stop (as will be described) holding the plunger from movement to the right caused by air pressure outside of the syringe. The vacuum is preferably created prior to introduction of the sampler into the body. At this point the catheter 14 contains atmospheric air. Depression of the valve cap 36 as shown in FIG. 10 when the catheter is within the body collection area 12, which can be done by the same hand of a user which is also manipulating the catheter 14 and without the need for a second hand, transfers the vacuum from the vacuum chamber 40 to the catheter 14 pulling materials and samplings from the body into the catheter as best shown in FIG. 10.

The syringe 16 is of conventional design and has a plunger 46 best shown in FIGS. 1, 2, and 5-7 and has an added stop structure.

The plunger 46 has an end thumb plate disk 41 with crossed planar walls 42 and 43 of conventional design and carries a plunger end cap 44 of conventional design. The plunger end cap has a vacuum seal through a resilient grommet such as 45 on the inside barrel of a circular axially extending syringe. A point of novelty in the syringe portion of this device resides in the first stop 50 which is an elongated plastic body 51 having a flat shape with a reinforcing rib 52. The body 51 has hooked end portions 53 and 54 which are preferably resiliently snapped and resiliently snapped and attached to the walls 42-43 of the plunger and held against the end disk 41 by a knob 80 of wall 42. Alternately, the body 51 can be adhesively attached to walls 42-43. The body 51 extends to an upwardly rising triangular cross-section portion 55 having a stop end wall or rib 56 and a resilient release or slide end 57 preferably in the shape of a triangle to allow sliding between walls 42 and 43. In use, as best shown in FIGS. 8-13, after the device is prepared for insertion in the body as shown in FIG. 8, and prior to insertion to the body, the plunger is withdrawn as shown in FIG. 9 to engage the stop wall or rib 56 thereby creating a vacuum in the cylindrical vacuum chamber 40 as shown in FIGS. 9 and 10. One hand of a user introduces the sampler into the body as shown in FIG. 10 and the sample is collected by moving the catheter while manually opening the valve 15 continuously or in

increments at spaced time periods. The vacuum can be maintained as shown in FIG. 11 and the stop 56 resiliently depressed (FIG. 12). The plunger can be moved to the right as shown in FIG. 13 after sample collection to expel the body materials obtained. The degree of vacuum is determined by the position of the plunger allowed by the first stop, or second stop as will be described. The further left as shown in FIG. 9, that the plunger 46 moves, the greater the vacuum available for use in the procedures of this invention to create a vacuum in the catheter.

FIG. 14 is an alternate embodiment of this invention wherein all parts are the same as the embodiment of FIG. 1 but a second stop 60 is used, substantially identical to the first stop. The stop wall or rib 61 of the second stop 60 is further to the left enabling a lesser predetermined vacuum to be obtained in the chamber 40 than would otherwise be obtained by the first stop. Thus, one can select which degree of vacuum one uses by use of the first and second stop as desired. Additional stops of varying kinds can be used in place of the specific resilient stops of FIG. 14 and greater or lesser predetermined values of vacuum can be obtained.

According to the method of this invention, the device or uterine sampler 10 is assembled either permanently or temporarily in the format of FIG. 1 and FIG. 2. Note that the actuating handle 36 is preferably aligned with the opening 20 in the sample collector (by being in the same circumferential position about the central axis of the catheter) so that even though the sample collector opening may be within the body, the user knows its positioning, which is aligned with the actuating handle. The device is actuated by forming a vacuum in the position of FIG. 11 and then the sampler 10 is introduced through the vagina into the uterus of an individual. The hand of the user which has done the introduction by grasping the barrel of the syringe, can then be used to compress the actuating handle and actuate a single vacuum in the catheter while moving the catheter opening 20 to collect samples within the uterus. Alternately, the user may actuate the handle more than one time with short single depressions and corresponding resilient opening of the valve to provide alternate vacuums as the sampler is moved from place to place in the uterus. The uterine sampler is then removed from the body and the plunger, as shown in FIG. 13, is moved to the right after resiliently depressing the stop member to expel the sample 11. If there has been a clogging of the vacuum catheter, the material collected may be expelled as shown in FIG. 13 and reused in the same

individual without re-sterilization since the same individual is involved in the same procedure. Here again, the vacuum is first established prior to entry of the catheter into the body and the steps are repeated.

It is a feature of this invention that all parts can be plastic and see through or transparent to enable viewing of the interior of the device at all times. In some case, portions may be opaque if desired. The specific dimensions of the vacuum can vary by varying the size of the syringe and catheter. In the preferred embodiment, the syringe is a 10 cc syringe while the catheter has an inside diameter of 2.0 milliliter and a length of 25 centimeters. The syringe can vary in many ways as for example glass, plastic, cylindrical, rectangular or other cross sectional shape and different size syringes can be used. In some cases, other vacuum devices can be used in place of the syringe if desired. In all cases, an actuating handle to allow use of the catheter by the hand of the user which is manipulating the overall device and collecting the sample is preferred and highly advantageous in devices of this type.

What is claimed is:

CLAIMS

1. A uterine sampler for collecting a sample of body material from the uterus of an individual,

said sampler comprising,

a vacuum uterine catheter defining a sampling opening, an elongated body extending from said opening to a proximal end with said body defining an axially extending vacuum passageway,

a vacuum device having a vacuum chamber for use in creating a vacuum in said vacuum passageway,

and a gate located between said vacuum device vacuum chamber and said vacuum passageway to interconnect and disconnect said chamber from said passageway by manipulation of said gate by the hand of a user.

2. A uterine sampler in accordance with claim 1 wherein,

said gate is a normally closed valve having an actuating handle, and

said vacuum device is a syringe carrying a stop to permit presetting of a vacuum in said syringe vacuum chamber.

3. A uterine sampler in accordance with claim 2 wherein said vacuum chamber has a greater volume than said vacuum passageway.

4. A uterine sampler in accordance with claim 2 wherein said stop provides a first vacuum in said chamber at a predetermined stop position, and

a second stop carried by said syringe for providing a second vacuum in said chamber.

5. A uterine sampler in accordance with claim 2 wherein said valve is resiliently biased to a closed position, and

said uterine sampler is sized and arranged to permit introduction and posting of said device into a uterus and activation of said valve to create a vacuum in said passageway by the use of one hand of a user.

6. A uterine sampler in accordance with claim 2 wherein said valve is resiliently biased to a closed position separating said vacuum chamber and said vacuum passageway, and

said syringe includes a plunger to create a vacuum in said chamber when said valve is closed,

and a stop for said plunger to determine the value of said vacuum in said chamber,

said valve permitting alternate actuation to permit alternate periods of sample collection.

7. A uterine sampler in accordance with claim 6 wherein said catheter has a material collecting opening at a distal end thereof, said opening defining a rim having an interior diameter and an exterior diameter,

said opening at said distal end extending outwardly from said interior diameter to said exterior diameter.

8. A uterine sampler in accordance with claim 7 wherein said catheter has a length of at least 10 centimeters and is axially inscribed with indicia indicating depth of penetration along a central axis of said catheter.

9. A uterine sampler in accordance with claim 6 wherein said valve includes a button handle spring biased to a closed position and located intermediate said syringe and catheter to permit manipulation of said syringe catheter and valve by a hand of a user.

10. A uterine sampler in accordance with claim 2 wherein said catheter, valve and syringe are joined together at Luer locks.

11. A uterine sampler in accordance with claim 9 wherein said catheter, valve and syringe are joined together by an adhesive bond.

12. A uterine sampler in accordance with claim 1 wherein a second stop is provided to provide a second vacuum in said vacuum chamber different than a vacuum provided by said first mentioned stock.

13. A uterine sampler in accordance with claim 1 wherein said catheter has an overall length of from 20 to 30 centimeters.

14. A uterine sampler in accordance with claim 7 wherein said catheter has axially aligned distance indicia.

15. A uterine sampler in accordance with claim 1 wherein said stop is mounted on a plunger axially aligned with a long axis of said syringe to create a vacuum in said syringe by withdrawal of said plunger from a closed position, said stop being spring biased to a stop position preventing movement of said plunger towards a vacuum created in said syringe by withdrawal of said plunger.

16. A uterine sampler in accordance with claim 15 wherein said stop comprises a resilient angled section having a forward edge adapted to be biased against a portion of said plunger with side edges mounted on support provided by said plunger and an end fixed to said plunger whereby movement of said angled portion of said stop beyond an end of a proximal end of said syringe activates said stop to prevent reversal of plunger movement.

17. In a method of obtaining a material sample from the uterus of an individual, the steps comprising, introducing into the uterus of an individual, an elongated catheter having a sample collecting opening aligned with a vacuum passageway,

said passageway being interconnected with a preset vacuum in a vacuum device separated from said vacuum passageway by a valve, said vacuum device, valve and catheter being sized and dimensioned to allow manipulation by a single hand of a user,

inserting said catheter into said uterus to a predetermined depth, manipulating said valve to create a vacuum in said vacuum passageway, which vacuum is derived from said vacuum device having a predetermined preset vacuum,

withdrawing said syringe as sample materials are collected.

18. A method in accordance with the method of claim 17 wherein said valve is manipulated from an open and closed position to alternately collect and stop collecting samples from said uterus as said catheter is withdrawn.

19. A uterine syringe in accordance with claim 6 wherein said catheter is formed of a polycarbonate material having a desired stiffness and being reusable.

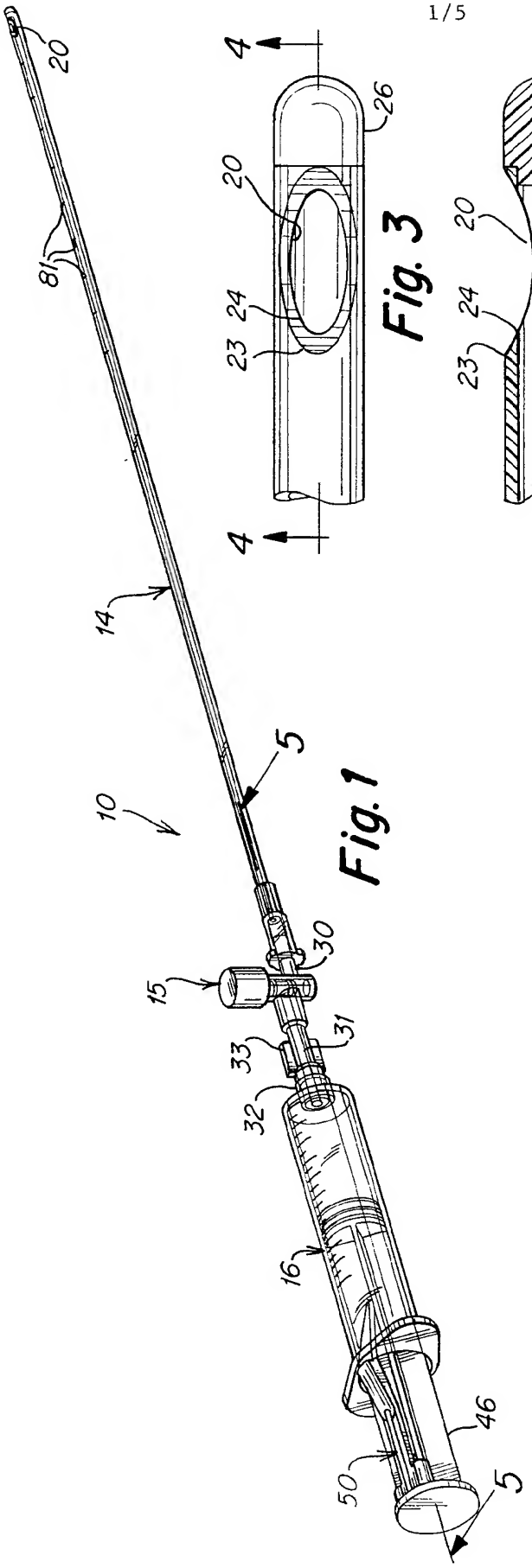

Fig. 1

Fig. 3

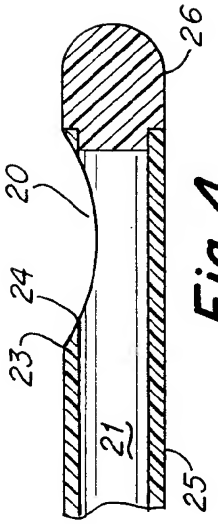

Fig. 4

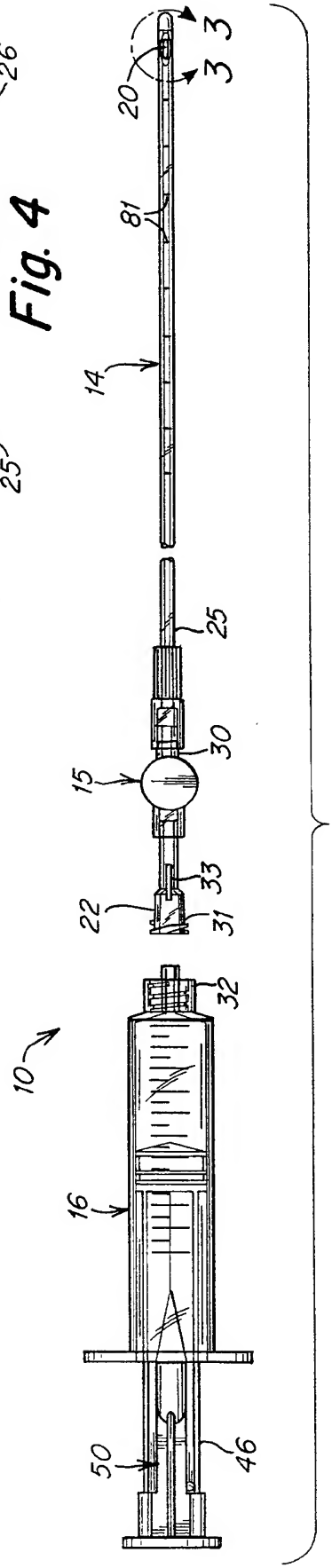

Fig. 2

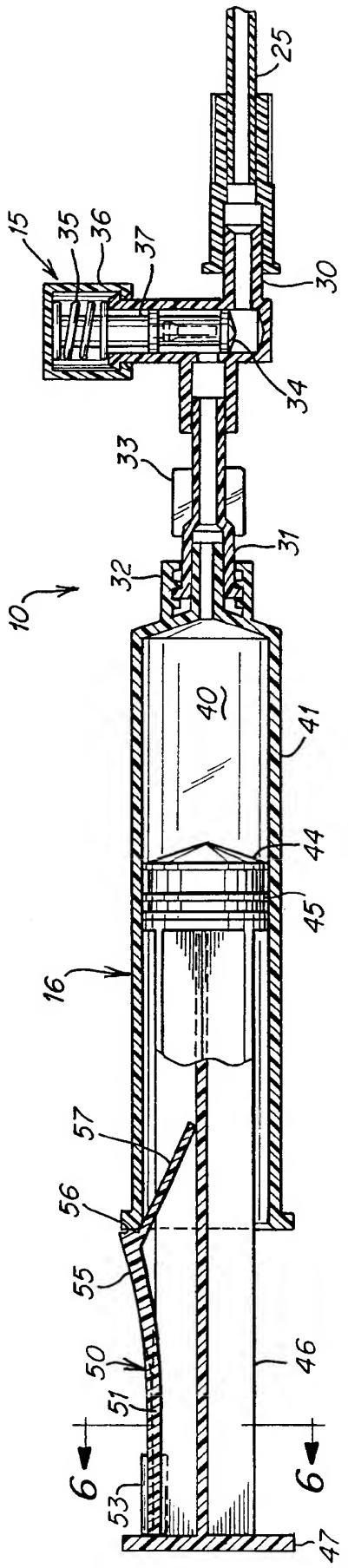

Fig. 5

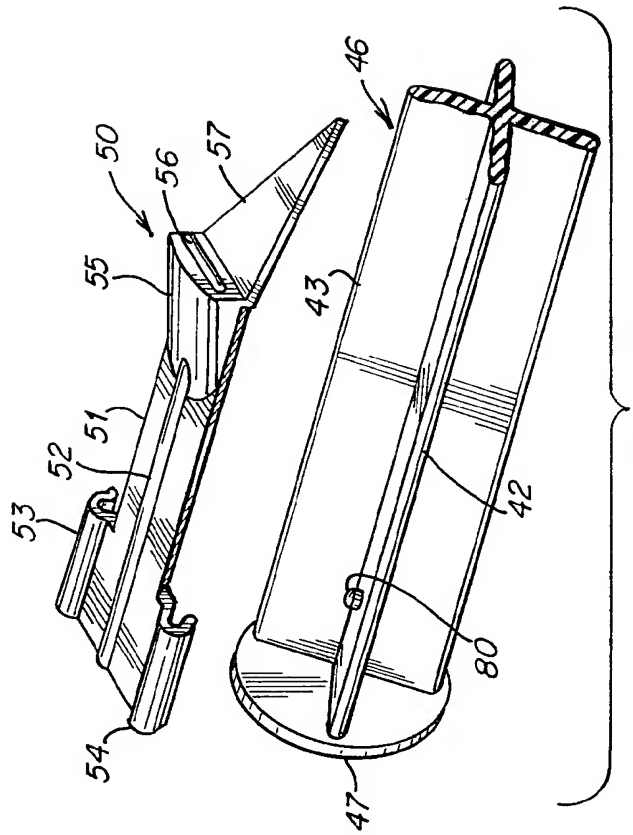

Fig. 7

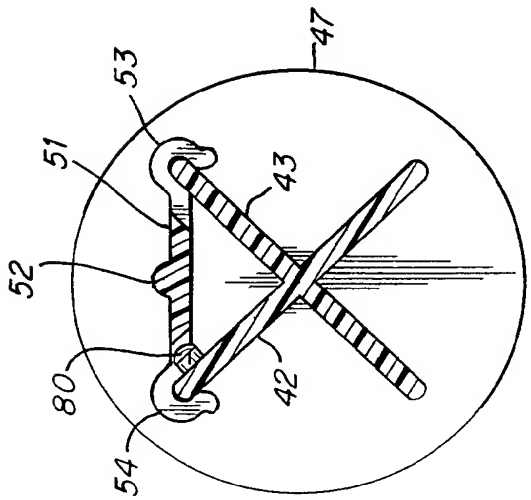

Fig. 6

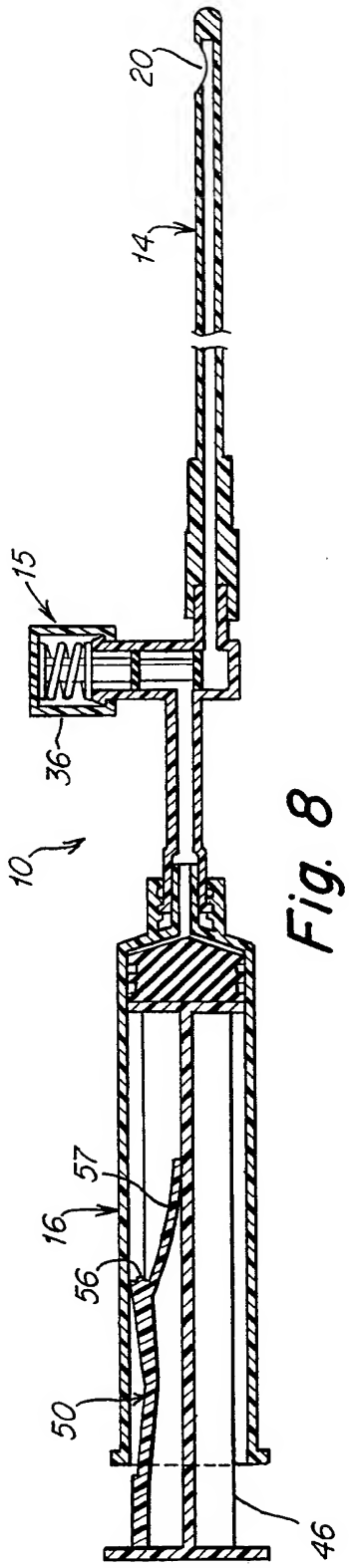

Fig. 8

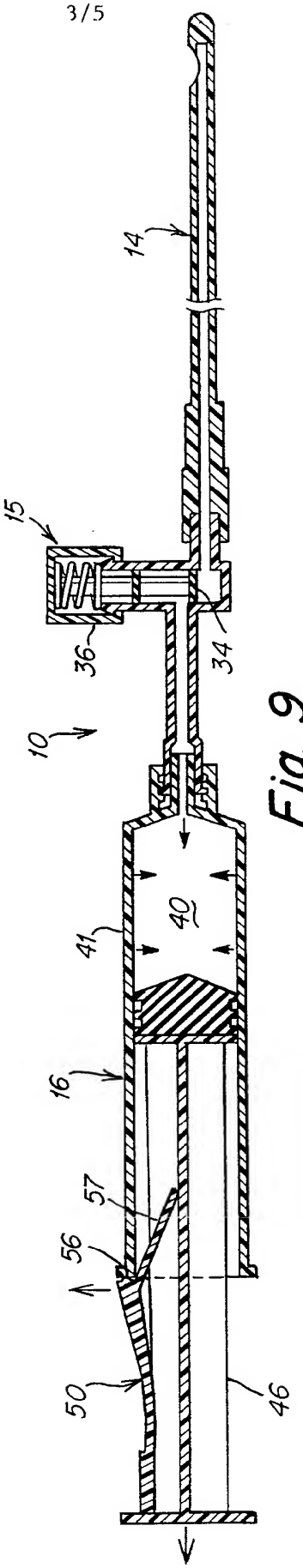

Fig. 9

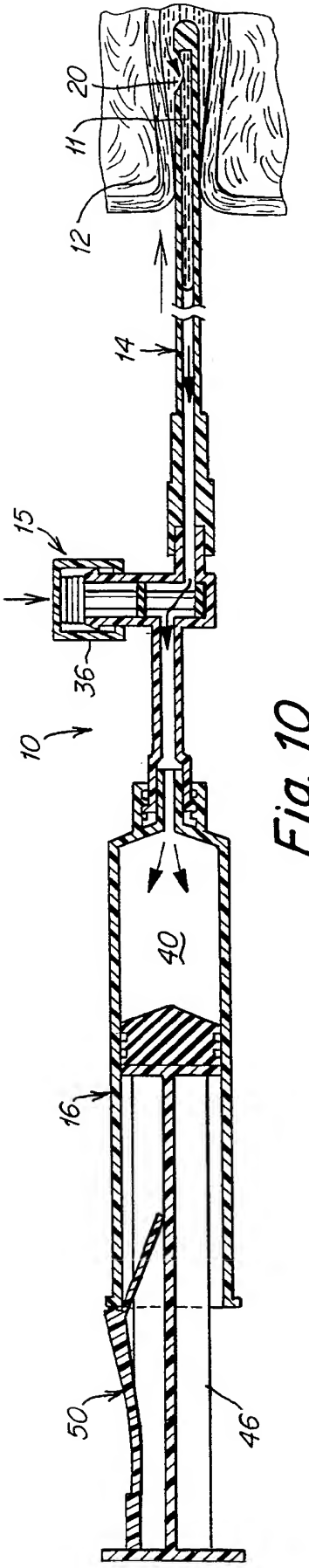

Fig. 10

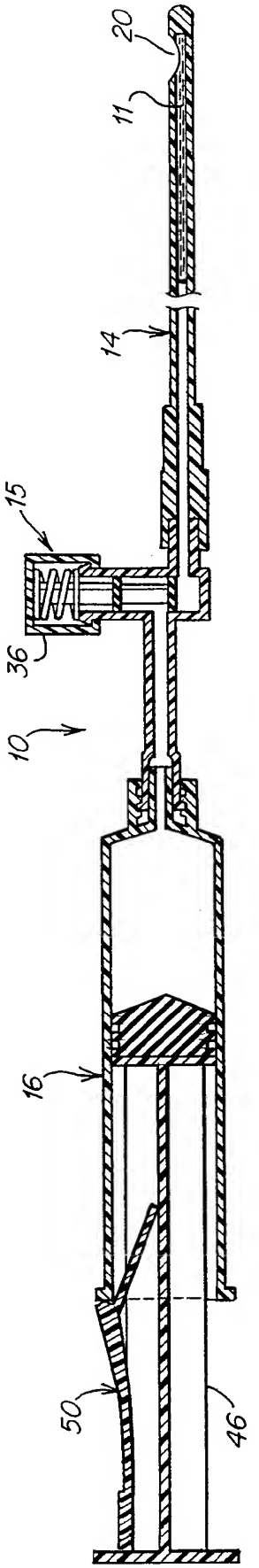

Fig. 11

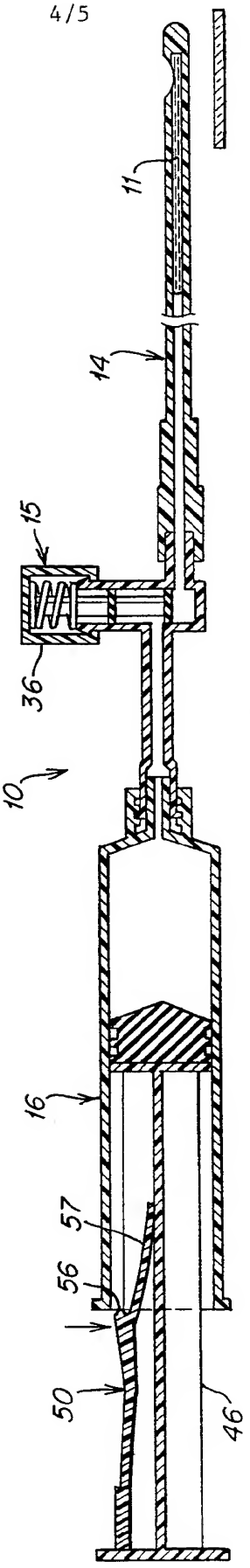

Fig. 12

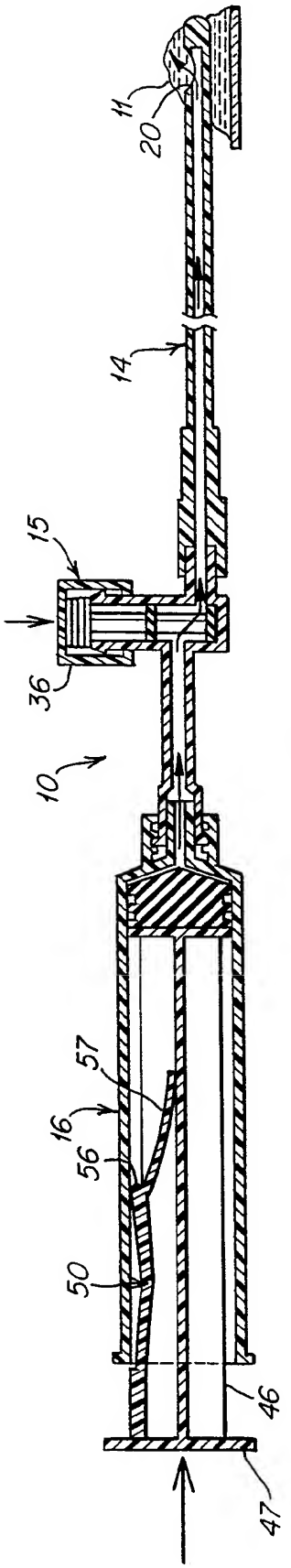

Fig. 13

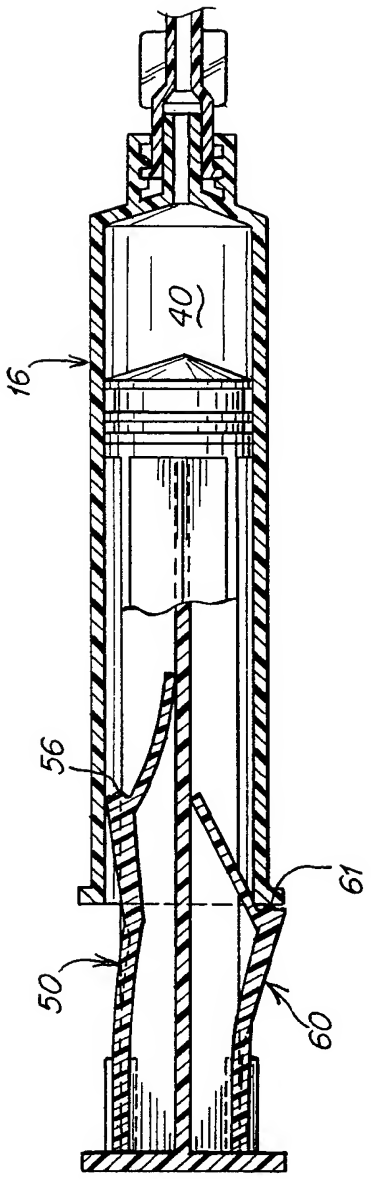

Fig. 14

INTERNATIONAL SEARCH REPORT

Ir. .ational Application No
PCT/US 01/03093

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 549 554 A (MARKHAM CHARLES W) 29 October 1985 (1985-10-29) column 6, line 56 -column 7, line 38; figure 4 ---	1-16,19
Y	US 5 485 853 A (STUBBS GEORGE) 23 January 1996 (1996-01-23) abstract column 2, line 36 - line 40; figure 1 ---	1-16,19
A	GB 1 441 387 A (PARKINSON P I) 30 June 1976 (1976-06-30) page 2, line 17 - line 57; figures 1,2 ---	4,12,15, 16
A	WO 86 07532 A (UNIV MINNESOTA) 31 December 1986 (1986-12-31) abstract; figures 1,8 --- -/--	1

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search	Date of mailing of the international search report
18 May 2001	28/05/2001

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